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| 10/697,908 | 10/29/2003 | Jon Faiz Kayyem | A-67499-2/RMS/RMK/SPL/463 | 9212 |

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EXAMINER

LU, FRANK WEI MIN

| ART UNIT | PAPER NUMBER |
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1634

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,908

Applicant(s)

KAYYEM, JON FAIZ

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informality: "FIGS. 3A, 3B, and 3C" should be "FIGS. 3A, 3B, 3C, and 3D" in page 3, line 10. Appropriate correction is required.

Claim Objections

2. Claim 4 is objected to because of the following informality: "EFS" is an abbreviation. It can only be used after whole name of "EFS" appears once.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

4. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Duong *et al.*, (US Patent No. 6,740,518 B1, priority date: September 17, 1998).

The applied reference has a common inventor, Jon Faiz Kayyem with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior

art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Duong *et al.*, teach a method of determining the presence of target analytes in a sample comprising: a) applying said sample to an array comprising a plurality of electrodes, wherein at least one electrode comprises an assay complex comprising: i) a capture binding ligand covalently attached to said electrode; ii) a target analyte; and iii) an electron transfer moiety wherein each electrode comprises a self-assembled monolayer; b) applying an input waveform to said electrode to generate an output waveform comprising at least one harmonic component, having a harmonic number greater than or equal to two; c) detecting said output waveform at said electrode; and d) analyzing said harmonic component with harmonic number greater than or equal to two to determine the presence of said target analytes (see column 109, claim 1 and column 10, second paragraph).

Regarding claim 1, since Duong *et al.*, teach applying an input waveform to said electrode to generate an output waveform comprising at least one harmonic component, having a harmonic number greater than or equal to two wherein said electrode in circuit boards comprises an assay complex comprising: i) a capture binding ligand covalently attached to said electrode; ii) a target analyte; and iii) an electron transfer moiety wherein each electrode comprises a self-assembled monolayer (see column 10, second paragraph, columns 101 and 102, and column 109, claim 1), Duong *et al.*, disclose applying an initial signal (ie., an input waveform) to a tissue collection device (ie., a circuit board) comprising an electrode comprising a self-assembled

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monolayer and an assay complex comprising a capture binding ligand, said target analyte, and an electron transfer moiety as recited in claim 1. Since Duong *et al.*, teach detecting said output waveform at said electrode and analyzing said harmonic component with harmonic number greater than or equal to two to determine the presence of said target analytes (see column 109, claim 1) and the input and output signals taught by Duong *et al.*, are used to measure electron transfer of electron transfer moiety, Duong *et al.*, disclose detecting electron transfer between said electrode and said electron transfer moiety as recited in claim 1.

Regarding claim 2, Duong *et al.*, teach that said sample is blood (see column 5, lines 19-38).

Regarding claims 3 and 4, Duong *et al.*, teach that said self-assembled monolayer comprises insulators and an EFS (see columns 12 and 13).

Regarding claim 5, Duong *et al.*, teach that said target analyte is nucleic acid (see column 109, claim 2).

Regarding claim 6, Duong *et al.*, teach that said capture binding ligand is a capture probe (see column 26, lines 47-60).

Regarding claim 7, Duong *et al.*, teach that said assay complex comprises a label probe comprising said electron transfer moiety (see column 37, lines 26-52).

Regarding claim 8, Duong *et al.*, teach that said electron transfer moiety is ferrocene (see column 41).

Therefore, Duong *et al.*, teach all limitations recited in claims 1-8.

5. Claims 1-8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

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The above patent (US Patent No. 6,740,518 B1) with priority on September 17, 1998 teaches all limitations recited in claims 1-8 (see above). However, inventors Duong, H., O'Connor, S., Terbrueggen, R., Olsen, G., and Litvack, J. are not listed in above patent, they should be considered as inventors of this instant application. Please give explanation.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 13 of U.S. Patent No. 6,740,518 B1 in view of Rubinstein *et al.*, (US Patent NO. 5,108,573, published on April 28, 1992).

Regarding claims 1 and 5, since U.S. Patent No. 6,740,518 B1 teach AC input and output waveforms are used to detect electron transfer (see columns 96 and 67), steps c) and d) of claim 1 and claim 15 of U.S. Patent No. 6,740,518 B1 teach b) of claim 1 in this instant application. Claim 2 of U.S. Patent No. 6,740,518 B1 teaches all limitations of claim 5 of this instant application.

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Claims 1, 2, and 13 of U.S. Patent No. 6,740,518 B1 do not disclose a self-assembled monolayer as recited in claim 1 of this instant application.

Rubinstein *et al.*, teach that the molecules of a self-assembled monolayer on a metal electrode facilitate and regulate the bonding between the modified metal surface and the growing phase of the conducting polymer (see column 4, lines 16-30).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have formed the method recited in claim 1 of this instant application by incorporating a self-assembled monolayer into an array complex recited in claim 1 in view of claims 1, 2, and 15 of U.S. Patent No. 6,740,518 B1 and Rubinstein *et al.*. One having ordinary skill in the art has been motivated to do so because incorporation of a self-assembled monolayer on a metal electrode would facilitate and regulate the bonding between the modified metal surface of the electrode and a conducting polymer (see Rubinstein *et al.*, column 4, lines 16-30). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to incorporating a self-assembled monolayer into an array complex recited in claim 1 in view of claims 1, 2, and 15 of U.S. Patent No. 6,740,518 B1 and Rubinstein *et al.*.

Conclusion

8. No claim is allowed.
9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November

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15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is 571-272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu
PSA
August 6, 2004

FRANK LU
PATENT EXAMINER